4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Request for Notification from Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on the Tobacco Products Scientific Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that industry organizations interested in participating in the selection of a nonvoting industry representative to represent the interests of tobacco growers, to serve on its Tobacco Products Scientific Advisory Committee, notify FDA in writing. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for the upcoming vacancy effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent the interests of tobacco growers must send a letter stating the interest to FDA by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], for the vacancy listed in the notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by

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[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: All letters of interest and nominations should be submitted in writing to TPSAC@fda.hhs.gov, or by mail to Caryn Cohen (see FOR FURTHER INFORMATION CONTACT).

FOR FURTHER INFORMATION CONTACT:

Caryn Cohen,

Center for Tobacco Products,

Food and Drug Administration,

9200 Corporate Blvd.,

Rockville, MD 20850,

1-877-287-1373 (choose Option 4),

FAX: 240-276-3655,

TPSAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency requests nominations for a nonvoting industry representative on the Tobacco Products Scientific Advisory Committee to represent the interests of tobacco growers. Elsewhere in this issue of the Federal Register, FDA is publishing a separate document announcing the Request for Notification for Voting Members on the Tobacco Products Scientific Advisory Committee.

I. Tobacco Products Scientific Advisory Committee

The Tobacco Products Scientific Advisory Committee (the Committee) advises the

Commissioner of Food and Drugs (the Commissioner) or designee in discharging

responsibilities as they relate to the regulation of tobacco products. The Committee

reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information and recommendations to the Commissioner. The Committee includes three nonvoting members who represent industry interests.

These members include one representative of the tobacco manufacturing industry, one representative of the interests of tobacco growers, and one representative of the interests of the small business tobacco manufacturing industry. The representative of the interests of the small business tobacco manufacturing industry may be filled on a rotating basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Committee. With this notice, nominations are sought for one representative of the interests of tobacco growers, and an alternate to this representative.

II. Selection Procedure

Any industry organization interested in participating in the selection of appropriate nonvoting member(s) to represent industry interests should send a letter stating that interest to the FDA contact (see FOR FURTHER INFORMATION CONTACT) within 30 days of publication of this document (see DATES). Within 50 days of publication of this document, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days of the receipt of the letter, to serve as the nonvoting member to represent the interests of the tobacco growers on the Committee. The interested

organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self-nominate and/or organizations may nominate one or more individuals to serve as a nonvoting industry representative (for the roles specified previously in this notice). Nominations must include a current resume or curriculum vitae of the nominee including current business address and/or home address, telephone number, email address if available, and the role for which the individual is being nominated. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.)

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: September 25, 2012

Jill Hartzler Warner, Acting Associate Commissioner for Special Medical Programs.

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